

Walk, Roger A.

From: Kobal, Gerd
Sent: Thursday, May 01, 2003 5:19 PM
To: Culley, Liz; Davies, Bruce D.; Willard, Howard A.; Solana, Rick P.; Nyffeler, Urs
Cc: Walk, Roger A.; Lau, Raymond W.
Subject: RE: Review of Cessation Web Review

Dear Liz,

Maybe there is some confusion, indeed. Let me briefly outline what a scientific review is thought to be among scientists. I am speaking of experience I have gathered in reviewing scientific publications for approx. 15 journals (Brain Research, Pain, Neuroscience Letters, Psychophysiology, etc.), I was on the editorial board of Chemical Senses for approx. 10 years and I have reviewed grant applications submitted to the NIH and their Swiss, Austrian, and German equivalents.

A journal - if the editor in chief is very pushy - gives a reviewer usually 2-4 weeks to review a paper of 10-12 pages. The process consists of thorough reading, understanding every sentence and looking critically at every word as if one would be co-authoring the paper and be responsible for every single statement. The literature cited has to be reviewed as well. Some cited papers may be known very well to the reviewer, others have to be read again and maybe even the citations in the cited paper have to be checked not only for correctness but also for their scientific value in the chain of arguments. If you are only a semi-professional in the field this takes longer compared to the time an expert needs who is working in the field for 10 years and even longer. So that is why the editors of journals have a data base of all the leading experts in the different fields of research - and they try to get the real peers in the field. That is also why scientists are so proud to have publications in peer reviewed journals because their findings are the 'truth' as long as nobody has contradicted them in another peer reviewed publication. WSA is following the same procedure in reviewing our scientific work and the work of others. This procedure and the time needed for this has to be taken into account if one asks for a scientific review.

We feel responsible for what we agree upon and I only wanted to make clear that Bruce's, Roger's and my comments are based on this type of approach. We will go on working on the text of the smoking cessation website in case it is thought to be a living document expressing our actual view of available information on smoking cessation.

However, as we have stated, it would be very helpful, if we could find a real expert in the field of smoking cessation who is willing to look at the material and gives us his opinion. So far, we have talked to Jed during our last meeting several weeks ago about this in more general terms and he has expressed his willingness to help even in writing a booklet himself with some co-authors. But as I stated in a meeting back in December 2002, a project of this type could take probably more than 6 months.

We are very proud of being partners in the smoking cessation program as we see it as the ultimate approach in reducing risk/harm which is the goal of our work. But if you ask a scientist a scientific question don't be surprised that you get a scientific answer.

Gerd

-----Original Message-----

From: Culley, Liz
Sent: Wednesday, April 30, 2003 11:58 AM
To: Davies, Bruce D.; Fuller, Stuart G.; Willard, Howard A.; Solana, Rick P.; Nyffeler, Urs; Kobal, Gerd
Cc: Walk, Roger A.; Lau, Raymond W.
Subject: Re: Review of Cessation Web Review

I believe there must be some confusion. First, wsa needs to be a partner in this process and is who we are looking to for technical and factual guidance. I believe stuart also talked to you about approaching jed to review the site as well. Our timing is. being driven by several crossfunctional and coordinated events as you know from our

conversations. But we won't solve this on e-mail. Let's plan on a conversation with urs, rick, howard and us to figure out how we better connect wsa as a partner in cessation.

Sent from my BlackBerry Wireless Handheld

-----Original Message-----

From: Davies, Bruce D. <Bruce.D.Davies@pmusa.com>
To: Fuller, Stuart G. <Stuart.G.Fuller@pmusa.com>; Culley, Liz <Liz.Culley@pmusa.com>; Willard, Howard A. <Howard.A.Willard@pmusa.com>; Solana, Rick P. <Rick.P.Solana@pmusa.com>; Nyffeler, Urs <Urs.Nyffeler@pmusa.com>; Kobal, Gerd <Gerd.Kobal@pmusa.com>
CC: Walk, Roger A. <Roger.A.Walk@pmusa.com>; Lau, Raymond W. <Raymond.W.Lau@pmusa.com>; Davies, Bruce D. <Bruce.D.Davies@pmusa.com>
Sent: Wed Apr 30 10:55:08 2003
Subject: Review of Cessation Web Review

Dear Stuart,

Sorry for the delay. Here are my comments concerning Revision J of the Smoking Cessation Website. They are attached as a file to this message. I will also forward comments I have received from both Roger and Raymond in separate email messages.

In addition, at the end of this message, I have appended a response I received from Gerd. I have to tell you that we both have some reservations about the material. First, let me make sure you understand that our review, particularly in the short time frame we had, was basically to look for typos, inconsistencies and all the other pretty obvious things that need to be addressed. It should by no means be construed that we have conducted the type of SCIENTIFIC review that we normally apply to documents such as this. But as we discussed in a phone call with Roger, you folks own the website material and are responsible for it's content and accuracy. I think it is fair to say that if WSA, and specifically Roger, were responsible, the review process, and by necessity the time frame for review, would be much more extensive and probably include an external review by experts in the field. I also understand from previous conversations that you folks don't feel that you have this time. I just wanted to make sure you understand that it was impossible for us to do a scientific review in the time frame you require.

We do have an option for you. As you know, we have a contact with a noted expert in the field. In addition, we have a signed confidentiality agreement with that individual. We would be more than willing to submit the latest draft of the website material to him for review. Gerd, Roger and I have discussed this and can anticipate three outcomes that I will mention below to help guide you in this decision.

1. We could anticipate that the reviewer could complete a review in 2 weeks and if in complete agreement with the content and approach, would return comments, minor corrections and suggestions within another 2 weeks.
2. Again the review could be complete in 2 weeks and he could completely reject the content and approach.
3. Review in 2 weeks, but with sufficient concerns about approach and content that it might take 4-6 months, working with the expert and his contacts, to produce a product with the highest potential of helping smokers to quit.

I realize you folks are very cramped for time to get this website on line, but I really suggest you discuss this and get back to us. We could call today to start the process.

Another question that Gerd and I had concerned the dynamics of the website information. For example, when it is launched, will there be anything on the site to say that it is a continual work in progress with changes being made as new information becomes available? Similarly, will we mention that it is a "test" site the effectiveness of which will be monitored and tested as time goes by and that changes will be made dependent upon those analyses? I am sure you intend to keep the site up to date on a continual basis. We also discuss how it might be useful to go with the site material as it stands as a "first approach" and follow up with the detailed analyses suggested.

So in summary, you should now have all of our editorial comments. Again, we were unable to complete a scientific review of the material.

Bruce

Bruce D. Davies, Ph.D.
Principal Scientist
Worldwide Scientific Affairs
Philip Morris USA

Comments from Gerd Kobal

thank you for sending us the different and updated versions of the website on smoking cessation.

Unfortunately, we only had a couple of days to look at it during the time we were engaged in other work we have to do.

As a consequence, a thorough scientific review was not possible in this short period of time.

In summary, we cannot say that we discovered major flaws or mistakes. Minor ones have been reported to you and Roger Walk and Raymond Lau have been very helpful in doing this.

My concerns are more related to the process of information selection. I can anticipate a situation where we will be asked why we put some information e.g. on page 2 and another piece of information on page 4. The arrangement of information and the sequence of statements is - as we all know from journalism - part of the information, too.

General statements might sound just nice, e.g.

"By understanding the options, how they work, and getting the advice of your doctor, you can find the way to quit that's right for you."

This implicitly suggests that there is 'a way that's right'. Looking at the low rate of quitting success in the literature one could easily come to the conclusion that there is practically no right way at all and that success rates are not much higher than placebo rates. In addition, what is the scientific evidence for different efficacies of therapies for different groups of people or individuals. Do I have scientific certainty to say nicotine patches don't work so good in these individuals but much better in those? Is there clear evidence for responders and non-responders?

Another sentence "These five steps are based on the idea that every quitting experience will include a few challenges". "few" means in this context that there are only few challenges and not many. Few also might suggest that they are quite easy to overcome while in reality some people never overcome one of these challenges.

If we assimilate the (hopeful) tone of other publications and advices given by public, non-profit or even governmental organizations it might not have the same meaning if we - P. Morris USA - say this.

Since we - i.e. Bruce and I - have not been involved in the creation of the website nor in outlining it, I would be more happy if an external expert would review the site

and tell us his opinion. As you know we have a confidentiality agreement with a key smoking cessation expert and he might be willing to have a look at the product to give us some feed back on how the site would be perceived from somebody outside the company.

Taking all aspects into consideration, we only could provide some ideas and maybe editorial comments but cannot look at the document as something that is approved formally by our group or WSA.

Gerd

Gerd Kobal MD, PhD, Professor of Pharmacology

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